IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David B. Volkin et al.	
Serial No. to be assigned	Art Unit: <u>1632</u>
Filed: For: POLYNUCLEOTIDE VACCINE FORMULATION	Examiner: Anne Marie Sabina Wehbe
Commissioner for Patents	

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR 1.97**

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
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Pursuant to the waiver by the Office of the re	equirement under 37 CFR 1.98 (a)(2)(i) dated July 11, 2003,
g date of this application is after June 30, 2003,	copies of each cited U.S. patent and each U.S. patent application
on are not enclosed herewith.	
DATE OF DEPOSIT AND A GENT A GENT AND A GENT AND A GENT A GENT AND A GENT A GENT A GENT A GENT AND A GENT A GENT A GENT A	I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, Virginia 22313-1450, on the date appearing below. MERCK & CO., INC. By Date

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited
by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120
are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	RELATED APPLICATION			
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE		
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If this is inconvenient, additional copies will be submitted upon request.

	6. In accordance with 37 C.F.R. 1.97, (check one)
\checkmark	the attached information is filed within three months of the filing date of the captioned case.
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	the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
	the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
	the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.
	Respectfully submitted,

J. Marstand

By: J. Mark Hand

Attorney For Applicant(s)

Reg. No. 36,545

MERCK & CO., INC. Patent Dept., RY60-30

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Date: JANUARY 26, 2004

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	nto titute for form 1449A/PTO		CLOSURE	Application Number	
STATEMENT BY APPLICANT	Filing Date	,			
	First Named Inventor	D. Volkin			
				Group Art Unit	1632
	(use as many she	eets as n	ecessary)	Examiner Name	Anne Marie Sabrina Wehbe
Sheet	1	of	3	Attorney Docket Number	19907YIACB

		U.S. Patent Document	0.5.17	ATENT DOCUMENTS	Date of Publication of
Examiner Initials*	Cite No.	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY
		5,703,057		Johnston et al.	12/30/1997
		5,593,972		Weiner et al.	01/14/1997
		5,703,055		Felgner et al.	12/30/1997
		5,739,118		Carrano et al.	04/14/1998
		5,928,865		Covacci	07/27/1999
		5,550,214		Eberlein et al.	08/27/1996
		5,928,900		Masure	07/27/1999
		5,981,505		Weiner et al.	11/9/1999
		6,004,799		Luciw et al.	12/21/1999
		5,925,362 5,808,024		Spitler, et al. Sasaki et al.	7/20/1999 9/15/1998

	FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Office	Foreign Patent Document Office Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		EP	WO96/00583	(if known)	Donnelly et al.	01/11/1996
		EP	0 620 277 A1		Donnelly et al.	10/19/1994
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Examiner Signature	Date Considered	

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COMPLETE IF KNOWN Substitute for form 1449A/PTO **Application Number** INFORMATION DISCLOSURE Filing Date STATEMENT BY APPLICANT First Named Inventor D. Volkin 1632 Group Art Unit (use as many sheets as necessary) Anne Marie Sabrina Wehbe Examiner Name 3 Attorney Docket Number of Sheet 19907YIACB

		OTHER NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	A	Haynes et al. Update on the Issues of HIV Vaccine Development', Ann Med. Vol 28, pp 39-41, 1996
	В	Chiang et al. Research and Development of Adjuvants for Cell Culture Derived Japanese Encephalitits VAccine', J. of Microbiology Immunology and Infection, Vol 31, No. 1, pp 58-63, 1998
	С	Hem et al. 'Accessibility of Antigen in Vaccines Prouded by in Situ Alum Precipitation', Vaccine Research, Vol 5, No. pp 187-191, 1996
	D	Brubaker et al. Th1-Associated Immune ResponesReplication Defective Herpes Simplex Virus', J. of Immunology, Vo 157, No. 4 pp 1598-1604, 1996
	E	Rinella et al. Elutability of Proteins from Aluminum-Containing Vaccine Adjuvants by Treatment with Surfactants', J. of Colloid and Interface Science, Vol. 197, No. 1 pp 48-56, 1998
	F	York et al. Immunomodulatory effects of HSV2for immunotherapy of recurrent HSV infection', Vaccine, Vol. 13, No. 17, pp 1706-1712, 1995
	G	McClements et al. Immunization with DNA vaccinesherpes simplex virus-2 disease' Proc. Natl. Acad. Sci., Vol. 93, pp 11414-11420, 1998
	Н	Manickan et al. 'Genetic Immunization Against Herpes Simplex Virus', J. of Immunology, Vol 155, NO. 1 pp. 259-265, 1995
	I	Berman et al. Protection from Genital Herpes Simplex Virus Type 1Glycoprotein D', Science, Vol 227, pp 1490-1492 1985
	J	York et al. Immunomodulatory effects of HSV HSV infection, Vaccine, Vol 13, pp 1706-1712, 1998
	к	Ross et al. Gene Therapy in the United States: A five-year Status Report', Human Gene Therapy, Vol 7, pp 1781-1790, 1996
	L	Dropulic et al. Gene Therapy for Human Immunodeficiency Virus Infection: Genetic Antiviral Strategies and Targets for Intervention', Human Gene Therapy, Vol. 5 pp 927-939, 1994
	М	Essex et al. Gene Therapy Against Retroviral Diseases', Leukemia, Vol. 9 Suppl. 1, S71-S74, 1995
	N	Durrani et al. Intranasal immunization with a plant virusthan oral immunization', J. of Immunological Methods, Vol. 220, pp 93-103, 1998
	0	Miller et al. Targeted vectors for gene therapy', FASEB J. Vol. 9, pp 109-199, 1995

Examiner Signature	Date Considered	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

	ubstitute for form 1449B/PTO			COMPLETE IF KNOWN		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			CLOSURE	Application Number		
			DIICANT	Filing Date		
			FLICANI	First Named Inventor	D. Volkin	
				Group Art Unit	1632	
	(use as many sheets	as n	ecessary)	Examiner Name	Anne Marie Sabrina Wehbe	
Sheet	3	of	3	Attorney Docket Number	19907YIACB	

NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.					
	P	Crystal et al. 'Transfer of Genes to Humans: Early Lessons and Obstacles to Cussess', Science Vol. 270, pp 404-410, 1995					
	Q	Deonarain, 'Ligand-targeted receptor-mediated vectors for gene delivery', exp. Opin. Ther. Patents, Vol. 8 pp 53-69, 1998					
	R	Verma et al. 'Gene Therapy-promises, problems and prospects', Nature, Vol. 389, pp 239-242, 1997					
	S	Orkin et al., 'Reports and Recommendations fo the Panelon Gene Therapy', NIH Report and Recommendations 1995					
	Т	Frynan et al. 'DNA Vaccines: protective imminizations by parenteral, mucosal and gene gun inoculations', Proc. Nat. Acad. of Sci., Vol. 90, pp11478-11482, 1993					
	U	Ulmer et al. 'Toward the development of DNA vaccines', Current Opinion in Biotechnology, Vol. 7, No. 6, pp 653-568, 1996					
	v	Benevisty et al. 'Direct Introduction of genes into rates and expression of the genes', Proceedings of the National Academy of Sciences, USA, Vol. 83, No. 24, pp 9551-9555, 1986					
	w	Gupta et al. 'Adjuvants for human vaccines - current status, problems and future prospects', Vaccine, Vol. 13, No. 14, p 1269, 1995					
	x	Yasutomi et al., 'A Vaccine-Elicited, Single Viral Epitope-Specific Tytotoxic TImmunodeficiency Virus Challenge', Journal of Virology, pp 2279-2284, 1995					
	Y	Ertl et al. 'Genetic Immunizaiton', Viral Immunology, Vol 9, pp 1-9, 1996					
	Z	Monteil et al. 'Genetic immunization of seronegative one-day-old pigletsfrom immune dams', Genetic Immunization, Vol. 27, pp 443-452, 1996					
	AA	Golding et al 'The Potential for Recruiting Immune Responses Toward Type 1 or Type 2 Cell Help', American Society of Tropical medicine and Hygiene, pp 33-40, 1994					
	AB	Xiang et al. 'Vaccination with a Plasmid Vector Carrying the Rabies Virus Glycoprotein Gene Induces Protective Immunity against Rabies Virus', Virology, Vol. 199, pp 132-140, 1994					
	AC	Marshall, 'Gene Therapy's Growing Pains', Science, Vol. 269, pp 1050-1055, 1995					
	AD	Restifo et al. 'Molecular Mechanisms Used by Tumors to Escape Immune Recognition: Complex Class I', Journal of Immunology, Vol. 14, pp 182-190, 1993					

Examiner Signature	Date Considered	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.